pacientes que realizaram CO na avaliação pré-transplante com a de 69 pacientes que não a realizaram. **RESULTADOS:** A análise do explante mostrou que, em ambos os grupos, CHC estava dentro dos critérios de Milão na maioria dos casos. Nenhuma das CO foi positiva para metástases. As taxas de sobrevida um e cinco anos pós-TxH foram de 81% e 69% nos que realizaram CO e de 78% e 62% nos que não a realizaram, respectivamente (p = 0,25). As taxas de recorrência, um e cinco anos após o TxH, em pacientes que realizaram CO foram de 4,8% e 10,7% e de 2,9% e 10,1% nos que não a realizaram, respectivamente (p = 0,46). **CONCLUSÕES:** A realização de CO gerou um gasto de US$ 27.582,914 e não apresentou uma relação de custo-efetividade.

PMD21

EVALUCIÓN ECONÓMICA COMPLETA DEL SISTEMA DE TERAPIA DE RADIACIÓN CON RAYOS X PARA EL TRATAMIENTO CÁNCER DE PRÓSTATA DE ALTO RIESGO EN MÉXICO

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OBJECTIVOS: Realizar una evaluación económica del sistema de terapia de radiación con rayos X vsacelerador lineal de alta energía en pacientes mexicanos, con cáncer de próstata de alto riesgo como tratamiento adjunto a terapia hormonal desde el punto de vista institucional. **METODOLOGÍAS:** Se realizó una revisión sistemática identificándose que la radioterapia de intensidad modulada (IMRT) es usada para el tratamiento del cáncer como adición a una terapia hormonal, los aceleradores lineales de alta energía utilizados en el país realizan esta técnica, de igual forma el sistema de tratamiento de radiación con rayos, por lo cual la eficacia y seguridad es la misma para ambas intervenciones, por lo cual se realizó una minimización de costos, comparando el costo total de ambos dispositivos en un horizonte temporal de 10 años, el costo anual equivalente y el costo por sesión de quimioterapia, se realizó un análisis de sensibilidad univariado. **RESULTADOS:** El sistema de terapia de radiación con rayos tuvo un costo de $132,969,600 y el acelerador lineal de alta tuvo un costo de $138,717,386.01, por lo cual hay un ahorro de $5,747,786.01 en los 10 años de horizonte temporal. En los resultados del costo anual equivalente, el costo de sesión de radioterapia y el análisis de sensibilidad se obtienen resultados similares por lo tanto se observa que en todos los casos el sistema de terapia de radiación con rayos X es una alternativa costo ahorradora respecto a las opciones actualmente utilizadas en las instituciones de salud públicas. **CONCLUSIONES:** El tratamiento de radioterapia con el sistema de terapia de radiación con rayos X, es una opción eficiente al compararlo con el acelerador lineal de alta energía ya que ambos dispositivos utilizan la misma técnica de radioterapia esto significa que tienen igual eficacia y seguridad, pero este nuevo dispositivo conlleva un menor costo de tratamiento.

PMD22

COST UTILITY ANALYSIS OF SPINAL CORD STIMULATION VS. REOPERATION IN THE TREATMENT OF FAILED BACK SURGERY SYNDROME IN COLOMBIA

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OBJECTIVES: Cost-Utility analysis of Spinal Cord Stimulation Rechargeable (SCS-RC) vs. reoperation in the treatment of Failed Back Surgery Syndrome (FBSS) in Colombia. **METHODS:** Through the adaptation of an economic model developed by Sigmatic Ltd t/a Abacus International for UK NICE submission, and previous data transferability analysis, a cost utility analysis was done comparing SCS-RC vs. Reoperation in patients with FBSS in Colombia. One short analytical decision tree and one long term Markov model were considered for model conceptualization of the health problem and treatment impact. The effectiveness and utility data was primarily based on data from the PROCESS trial combined with Colombian costing data. A 15 years horizon, a third party payer perspective and 3% discount rate for utilities and costs were assumed. The Health states considered, at annual cycles, were optimal pain relief, optimal pain relief with complications, sub-optimal pain relief, and sub-optimal pain relief with complications. Optimal pain relief occurs with a pain threshold of 50%. Incremental analysis along with univariate and probabilistic sensitivity analysis was done. **RESULTS:** SCS-RC had an incremental costs of US$11.223 and 1,09 incremental QALYs, with an ICER of US$10.293 which is far lower than the US$24.300 GDP Percapita recommended by the WHO as threshold for development countries and a 62,2% probability of been cost-effective, when probabilistic analysis was ran. **CONCLUSIONS:** SCS-RC showed a 62,2% probability of been cost-effective when compared to Reoperation in patients with FBSS in Colombia.

MEDICAL DEVICE/DIAGNOSTICS – Patient-Reported Outcomes & Patient Preference Studies

PMD23

PSYCHOMETRIC ANALYSIS AND VALIDATION OF THE PATIENT SATISFACTION WITH ORTHOPAEDIC AND PROSTHETIC MEDICAL DEVICES, MODUL CLIENT SATISFACTION WITH DEVICE (CSD)

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OBJECTIVES: Each Provider of Health Care Services (PHCS) is according to the law, obligated to manage its quality of health care services. To fulfil this role, it has to use a tool that is validated and territorially adapted. Outcomes of the survey reveal the weaknesses and the corrective measures can be taken. **METHODS:** The sample of patients with orthopaedic, neurologic and rheumatic diseases was from Specialized Hospital for Orthopaedic Prosthetics in Bratislava, Bratislava region, Slovak republic. It was made a translation and cross-cultural adaptation of CSD module into the Slovak language to evaluate weight, fit, durability, pain, abrasion, putting on device, comfort and look of orthosis and prosthesis medical devices. Extended psychometric analysis was done using the factor analysis (Horn´s Parallel Analysis, Exploratory Factor Analysis) and Rasch analysis (RA, Rating Scale model) (Scale diagnostic, Validity, Reliability, Dimensionality and Local independence, Differential item functioning (DIF)). **RESULTS:** Horn´s Parallel Analysis revealed one factor (loading factor >0.40). RA showed a correct functioning of the rating categories of the scale. As for the item fit, only one item 'It is easy to put on my device' slightly underfitted the model (Outfit MSQ = 0.720, Infit MSQ = 0.650) and item 'durability' overfitted the model (Outfit MSQ = 1.378, Infit MSQ = 1.291). The study showed a few similar allocations of items along the logit scale, weight and fit was easy to endorse, whereas the look and comfort of the orthosis were difficult to agree with. No local dependency was detected. The targeting of item difficulty to the patient ability was good. Omega reliability value of CSD-Sk was 0.9 (polychoric Cronbach's alpha level 0.9). No DIF was detected. **CONCLUSIONS:** Despite some limitations in terms of fit, psychometric properties of CSD-Sk are in line with previous analyses on the English, Swedish and Italian version of the tool.

PMD24

IMPROVING PATIENT QUALITY OF LIFE BY VERIFYING AND ENHANCING QUALITY OF ORTHOPAEDIC AND PROSTHETIC MEDICAL DEVICES

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OBJECTIVES: There is a lack of information about patient satisfaction with orthopaedic and prosthetic medical devices (OPMD). As they influence a compliance, tolerance and usefulness, it is important to obtain and valuate them. Also they can be useful for verifying and enhancing quality of OPMD, for improving quality management of health care provider as well as patient´s quality of life. **METHODS:** Evaluation of patient satisfaction with OPMD was realised on the sample of patients with orthopaedic, neurologic and rheumatic diseases from Specialized Hospital for Orthopaedic Prosthetics in Bratislava, Bratislava Region, Slovak Republic. It was used a translated and cross-cultural adapted module of Client Satisfaction with Devices (CSD-Sk). The weight, fit, durability, pain, abrasion, putting on device, comfort and look of OPMD were evaluated. It was used a 4 point Likert scale with answers strongly agree, agree, disagree, strongly disagree. **RESULTS:** Description of the study sample: age >60 n%=46.6, women n%=75.1, high school educated patients n%= 56.0. The most patients had problems with lower limbs (42.5%), followed by spine (26.9%) and combination lower limbs and spine (25.9%). In case of type of diseases the most patients had orthopaedic diseases (73.6%), combination orthopaedic and neurologic (13.5%) and neurologic diseases (7.3%). The most used OPMD were orthopaedic insoles (36.3%), waist belt (17.6%) and corset on the spine (5.2%). Overall patients were highly satisfied with OPMD. More than 50% responses on items were mostly strongly satisfied (63.2 – 51.8%), except durability (43.5%). The most negative responses were on fit (7.25%) and abrasion (6.22%). **CONCLUSIONS:** It was recorded a high satisfaction with OPMD among surveyed patients. Comparing our Resultsto the previous analysis in the world we can reveal higher level of patient satisfaction. Hopefully we can conclude that Health Care Provider manages good quality of OPMD and these regulations may contribute to patient´s satisfying quality of life.

MEDICAL DEVICE/DIAGNOSTICS – Health Care Use & Policy Studies

PMD26

ECONOMIC VALUE OF STEMI PROGRAM INVESTMENT IN SAO PAULO, BRAZIL

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OBJECTIVES: For Sao Paulo, evaluate the clinical and economic impact of investments in programs to a) increase rate of timely hospital admissions (within 12 hours of symptom onset) for STEMI patients, and b) manage more STEMI patients with PCI versus alternative approaches (e.g. thrombolytics, no reperfusion). **METHODS:** Data from the RBSCA Registry, DataSUS, and a private Sao Paulo hospital were modeled to quantify the impact from STEMI treatment scenarios year-over-year from 2013-2018. Model inputs included morbidity and mortality, labor productivity (average wage), direct costs, and burden of disease (measured by disability-adjusted life-years and value-of-statistical-life). Outcomes are calculated up to 1 year after initial MI for admitted versus non-admitted populations, the latter group being divided according to treatment pathway: PCI, thrombolytics, no reperfusion, or CABG. Prospective outcomes through 2018 were modeled to calculate the value of continued investment in STEMI management **RESULTS:** From 2013-2018, an investment of 1.2M USD (EKGs, education, ambulances) to increase STEMI utilization at current catheterization laboratories would result in 2,031 lives saved and 22.0 million USD cost savings. **CONCLUSIONS:** Expenditures to improve STEMI management strategies in Sao Paulo showed favorable economic outcomes and mortality reduction when more patients were managed with PCI, suggesting that continued national investment in STEMI management could further improve these rates, with greater cost savings achieved.

PMD27

CONSULTA AOS MEMBROS DE AGÊNCIAS INTERNACIONAIS DE ATS COMO ESTRATÉGIA DE INTERCÂMBIO DO CONHECIMENTO PRODUZIDO – O CASO DO PET-TC

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OBJETIVOS: Investigar entre as agências de Avaliação de Tecnologias em Saúde (ATS) a produção de estudos e a recomendação da utilização de PET-TC para o diagnóstico de metástases em pacientes com câncer de mama localmente avançado. **MÉTODOS:** Foi realizada consulta à INAHTA (The International Network of Agencies for Health Technology Assessment) e à REDETSA (Red de Evaluación de Tecnologias en Salud de las Américas), por meio de correio eletrônico, questionando a realização de estudos de ATS e de recomendações do PET-TC para o diagnóstico de metástases em

pacientes com câncer de mama localmente avançado. **RESULTADOS:** Treze agências membro da INAHTA (24% de taxa de resposta) de doze países responderam. Dessas, seis informaram não ter avaliado o PET-TC para essa finalidade: ARSENIP-S; CDE; CRD; DAHTA @ DIMDI; HIS e NHC. A agência G-BA enviou material em alemão, que não foi apreciado. E ainda, 6 membros enviaram estudos relacionados à pergunta em questão: ASSR; CADTH; IETS; KCE; NHMRC CTC; MaHTAS. Na REDETSA, cinco membros de quatro países responderam ao questionamento, sendo que o Ministerio de Salud de Paraguay e a agência canadense, INESSS, informaram não ter avaliado o PET-TC para essa finalidade. Outros três membros enviaram estudos relacionados à pergunta em questão: IECS; IETS e o Ministerio de Salud y Protección Social de Colombia. Foi realizada busca nas bases NICE, National Guideline Clearinghouse, Avalia-T e UpToDate. Em todos os estudos analisados não houve recomendação para o uso do PET-TC como primeira opção para o diagnóstico de metástases em pacientes com câncer de mama localmente avançado. Porém, algumas agências salientaram a sua importância na confirmação de imagens convencionais não conclusivas. **CONCLUSÕES:** A estratégia de consulta à INAHTA e REDETSA é uma ferramenta útil para mapear a produção de estudos e recomendações pelos outros países, permitindo comparabilidade e possibilidade de adaptação ao contexto local.

PMD28

ECONOMIC IMPACT OF A VOLUMETRIC INFUSION PUMP (INFUSOMAT® SPACE) + CENTRAL ALARM MANAGEMENT (ONE VIEW), IN THE RISK PREVENTION IN INFUSION THERAPY IN THE INTENSIVE CARE UNIT (ICU) IN MEXICO

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OBJECTIVES: Medication errors are the most significant cause of medical injuries. In an attempt to reduce infusion errors, smart pumps were developed. These new infusion systems include hospital defined drug libraries with established dosing limits and other clinical advisories integrated into the system. The INFUSOMAT® SPACE + the CENTRAL ALARM MANAGEMENT, OneView® is an infusion + a monitoring system that offers clinical and economic benefits by increase safety in delivering IV medications, reducing hospital length of stay, providing an advanced or faster response to emergencies and improving workflows in the ICU. This analysis aims to estimate the economic impact of this new system on driving care toward evidence-based standards from the perspective of public health system (IMSS). **METHODS:** An economic impact analysis was developed. In order to obtain system efficacy and safety evidence, a literature search was driven. For medical errors in Mexico associated to infusion pumps, a retrospective analysis of medical claims during the last 4 years was conducted utilizing data from the National Commission of Medical Arbitration (CONAMED). Costs of ICU per day and adverse events were obtained from the IMSS Finance Direction and the Groups Related to Diagnosis (GRD). Costs were reported in US dollars (1 USD = 15.42 MXN). **RESULTS:** The use of the INFUSOMAT® SPACE + CENTRAL ALARM MANAGEMENT (ONE VIEW) in comparison with the current infusion pumps used in the IMSS, lead to better benefits, clinical and economic. In adverse events avoided due the lack of monitoring (5% reduction) and the expected length hospital stay (2.4% lower). Such reduction could represents $99,984,542 USD and $4,999,227 USD in savings for the IMSS per year, respectively. **CONCLUSIONS:** Adopting the INFUSOMAT® SPACE + CENTRAL ALARM MANAGEMENT (ONE VIEW) will reduce adverse events and will significant lower the costs associated with longer patient stays and complications at the IMSS ICU.

DISEASE – SPECIFIC STUDIES

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

LA HIPOGLUCEMIA INCREMENTA EL GASTO EN SALUD Y DETERIORA LA PRODUCTIVIDAD DE PACIENTES CON DIABETES TIPO 1 Y TIPO 2

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La hipoglucemia es la dificultad más temida del tratamiento con insulina, con posible impacto social y sobre la utilización de recursos en salud, aspectos evaluados infrecuentemente.**OBJECTIVOS:** Describir el impacto de la hipoglucemia sobre el desempeño social y el uso de recursos en salud, en pacientes argentinos del estudio HAT. **METODOLOGÍAS:** Estudio internacional, no intervencional que evaluó hipoglucemia severa (HS) y no severa (HNS) en pacientes con DM1 y DM2 tratados con insulina, mediante cuestionarios de autoreporte: el 1° transversal retrospectivo sobre periodos de 6 meses (HS) y 4 semanas (HNS) y el 2° prospectivo de 28 días (HS e HNS). **RESULTADOS:** Participaron 1253 pacientes (DM1: 433, DM2: 823); en promedio, edad 41.7 y 63 años, duración de la diabetes 17.6 y 15.4 años y HbA1c 8.1% y 7.8% para DM1 y DM2 respectivamente. En el período retrospectivo 82.7% (DM1) y 48.6% (DM2) informaron al menos 1 HNS; 37.9% y 16.3% comunicaron HS. En el período prospectivo, 88.1% y 44.6% reportaron HNS, 21.5% y 8.5% HS para DM1 y DM2 respectivamente. En el período retrospectivo, 24(6.1%) pacientes y 16(3.2%) requirieron admisión hospitalaria, 13(3.4%) y 23(5%) asistieron a consultas adicionales y 75(19.6%) y 84(18.2%) se comunicaron telefónicamente con algún integrante del sistema de salud, debido a una hipoglucemia para DM1 y DM2, respectivamente. Desempeño laboral (período retrospectivo) los pacientes faltaron 3.1(3) y 5.8(7.9), llegaron tarde 3.5(3.9) y 6.9(9.4), se retiraron antes 10.5(53.5) y 4.7(8.4) (días en promedio [DS]) para DM1 y DM2 respectivamente. En el período prospectivo faltaron 2.5(3) y 2.7(1.2), llegaron tarde 1.4(0.9) y 1.3(0.5), se retiraron antes 1.7(1) y 1.3(0.5) días para DM1/DM2 respectivamente. **CONCLUSIONES:** En una muestra de personas de la Argentina con DM1 y DM2 tratados con insulina, la hipoglucemia generó mayor uso de recursos en salud y deterioró el desempeño laboral/académico de los pacientes.

PDB2

EFETIVIDADE E SEGURANÇA DA GLARGINA VS DETEMIR E NPH NO TRATAMENTO DE PACIENTES COM DIABETES TIPO 1 – REVISÃO SISTEMÁTICA E METANÁLISE

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OBJETIVOS: O uso dos análogos de insulina para o tratamento de diabetes mellitus tipo 1 (DM1) tem sido difundido, mas os reais benefícios terapêuticos ainda carecem de evidências. O objetivo deste estudo foi avaliar efetividade e segurança da Glargina comparada ao Detemir ou NPH no tratamento de pacientes com DM1. **MÉTODOS:** Revisão sistemática com metanálise de estudos de coorte e registro, disponíveis nas bases de dados PUBMED, LILACS, CENTRAL (acessados janeiro de 2015), incluindo busca manual e literatura cinzenta. A metanálise foi conduzida no software Review Manager® 5.2, no modelo de efeitos randômicos. Os desfechos primários avaliados foram: glicohemoglobina (HB1Ac), ganho de peso e ocorrência de hipoglicemias. A avaliação da qualidade metodológica foi realizada utilizando a escala Newcastle. **RESULTADOS:** De um total de 1.085 publicações, 15 estudos foram incluídos: 11 (Glargina vs. NPH) e 4 (Glargina vs. Detemir). Na comparação glargina e NPH, a metanálise favoreceu glargina nos desfechos HB1Ac (pacientes adultos) e episódios hipoglicêmicos (p< 0,05). Ao comparar glargina e detemir os resultados foram significativos para ganho de peso, episódios de hipoglicemia severa e controle da glicemia capilar, favorecendo detemir (p< 0,05). A qualidade metodológica dos estudos foi moderada, destacando que 40% estudos foram financiados pela indústria farmacêutica. **CONCLUSÕES:** Os resultados dos estudos incluídos expressam o uso dos análogos e NPH na "vida real". Mostram que a insulina glargina apresentou melhores resultados de efetividade e segurança em relação a NPH, mas quando comparada a detemir apresentou piores resultados para os principais desfechos. A recomendação dos análogos como terapia de primeira linha deve ser vista com cautela, considerando a pequena diferença entre os desfechos nas metanálises, os potenciais conflitos de interesse e o custo de tratamento frente às alternativas terapêuticas existentes.

PDB3

EFFICACY AND SAFETY OF ANTIDIABETIC DRUGS AVAILABLE ON BRAZILIAN PUBLIC HEALTH SYSTEM (SUS) – REGULAR INSULIN, NPH INSULIN, METFORMIN, GLIBENCLAMIDE AND GLICLAZIDE – IN TREATMENT OF TYPE 2 DIABETES (T2DM) - SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To evaluate the efficacy and safety of therapeutic alternatives provided in the SUS, in monotherapy and combinations for the treatment of T2DM. **METHODS:** Systematic review (SR) with meta-analysis of randomized controlled trials (RCTs) available in PubMed, LILACS, CENTRAL databases (October/2014), including manual and gray literature search. Meta-analysis was conducted in Review Manager®5.2 software by applying the random effects model. The primary outcomes were, concentration(%) of glycated hemoglobin (GHb), blood or plasma glucose concentrations and occurrence of adverse events. Methodological quality was assessed using the modified Jadad scale and Risk of bias according to the recommendations of the Cochrane Collaboration. **RESULTS:** There were included 33 RCT´s of the 9,715 achieved publications: 4 compared NPH Insulin + Regular Insulin (RI) vs. Glibenclamide, 1 (NPH + RI vs. NPH + Glibenclamide), 6 (NPH + IR vs. NPH + RI + metformin), 2 (NPH + RI + Glibenclamide vs. Glibenclamide + Metformin), 1 (NPH + Glibenclamide vs. RI + Glibenclamide), 1(Metformin vs. Gliclazide), 10 (Glibenclamide vs. Metformin) 1(Metformin vs. Metformin + gliclazide), 7 (Metformin vs Metformin + Glibenclamide), 10 (Glibenclamide vs Glibenclamide + Metformin) 3 (Glibenclamide vs. Gliclazide) and 1(Gliclazide vs. Glibenclamide + Metformin). The evidence points to satisfactory efficacy and safety profiles of the drugs available on SUS for the treatment of T2DM. Insulin preparations have greater GHb reduction capability, but a higher incidence of hypoclycemic episodes than oral antidiabetic agents, which have similar profile of efficacy and safety. Combination therapy followed a similar pattern. Studies on direct comparison between drugs support no sufficient evidence to rank then. **CONCLUSIONS:** Considering the efficacy and safety of medicines supplied by SUS, the choice of T2DM therapy depends on the stage of the disease and on patient's preferences. Insulin preparations should preferably be introduced to patients at more advanced stages of the disease.

PDB4

EFETIVIDADE CLÍNICA COMPARATIVA DO ANÁLOGO DE INSULINA GLARGINA PARA TRATAMENTO DE PACIENTES ACOMETIDOS POR DIABETES MELLITUS TIPO 1

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OBJETIVOS: Realizar análise de efetividade clínica comparativa do análogo de insulina de longa duração de ação glargina com a insulina NPH, durante 18 meses de acompanhamento de pacientes com diabetes mellitus tipo 1. **MÉTODOS:** Uma coorte prospectiva não concorrente de pacientes que receberam o análogo de insulina glargina incluídos no Protocolo Clínico e Diretrizes Terapêuticas (PCDT) da Secretaria Estadual de Saúde de Minas Gerais, Brasil. Para análise da efetividade clínica compararam-se os resultados laboratoriais de hemoglobina glicada (HbA1c) antes e após seis, 12 e 18 meses de uso de glargina. Avaliou-se, ainda, a redução das crises hipoglicêmicas e o controle glicêmico dos pacientes aos 18